REMARKS

Status of the claims

Claims 1-21 are pending in the application. Claims 1 and 6 have been amended herein. Support for the amendments to claim 1 may be found at least on page 6, first paragraph of the specification. No new matter has been added by way of these amendments. As such, entry thereof is respectfully requested.

Double patenting rejection

Claims 1-21 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of USP 7,462,701. Without acquiescing to the rejection, submitted herewith in view of the '701 patent is a terminal disclaimer. The rejection is thus rendered moot and withdrawal thereof is respectfully requested.

Rejections under 35 U.S.C.§103

Claims 1-4 and 6-20 remain rejected under 35 U.S.C.§103 as being obvious over Haynes et al. (USP '715) combined with Shani et al. (WO '174). Haynes et al. is asserted to teach an aqueous phase separation or purification system together with methods for their preparation and use. The systems of Hayes et al. are asserted to be based on polymer-ligand conjugates, wherein the polymer is an oligosaccharide and the ligand is an oligosaccharide binding protein, such as CBM. Following binding, the composition is removed from the oligosaccharide using a specific or non-specific protease. The system and methods of Haynes et al. are asserted to differ from the instant invention in failing to disclose the feature that the fusion proteins are expressed in transgenic plants or obtained from transgenic plants.

Shani et al. is asserted to teach a process of expressing a recombinant protein in a plant and a method of isolating the recombinant protein from the plant. The Examiner asserts that it would have been obvious to combine the method of Shani et al. with those of Haynes et al. with the motivation to do so being the teachings in the prior art of the advantages of fusion proteins comprising a CBD binding domain and proteolytic cleavage site for ease of isolation of the

heterologous protein and that plants represent an alternative expression system for the mass production of proteins.

Applicants again traverse this rejection. The present invention as encompassed by amended claim 1 is drawn to a non-denaturing process for obtaining a heterologous protein of interest produced in a plant, comprising

(a) providing a fusion protein comprising said heterologous protein fused to a carbohydrate binding module (CBM) intercepted by a proteolytic cleavage site, wherein the carbohydrate binding module does not bind to plant cell-wall material and wherein the fusion protein is soluble in a liquid phase obtained from adding extraction liquid to a disrupted plant material,

(b) contacting said fusion protein with a functional protease fused to a CBM, at conditions facilitating proteolytic cleavage by said protease, to cleave the CBM from the heterologous protein of interest,

(c) contacting the solution of CBM-protease, free CBM and heterologous protein of interest to a polysaccharide matrix, under conditions where the CBM-protease and free CBM binds to said polysaccharide matrix and where the heterologous protein of interest is not retained on said polysaccharide matrix,

(d) separating the non-bound heterologous protein of interest from the polysaccharide matrix,

(h)washing the polysaccharide matrix with the bound CBM-protease and CBM, with one or more suitable aqueous solutions,

(e) eluting the CBM-protease from the matrix by adjusting conditions effecting the release of said CBM-protease off the matrix; and

(f) optionally reconditioning said eluted CBM-protease, to retain its affinity to said polysaccharide matrix, such that the reconditioned CBM-protease can be re-used for subsequent repetition of the process defined by steps (a)-(g),

wherein said CBMs are capable of binding reversibly to a polysaccharide matrix and being released from such matrix by non-denaturing elution conditions.

The present invention is limited to CBMs which **do not bind to cell-wall plant material,** as indicated by amended claim 1. Shani fails to teach or suggest this feature. In fact, Shani teaches away from using any CBMs which would *not* bind to an insoluble cell wall plant material. The plant in Shani is homogenized to bring the fusion protein into contact with the cellulosic matter to form a fusion protein cellulosic matter complex. Page 1, lines 8-11, of Shani state that "the process exploits (i) the high affinity between cellulose binding peptides and cellulose; (ii) the inherent abundance of cellulose in planta" (emphasis added). Shani further states on page 1, lines 14-17, that the process employs "the isolation of a fusion protein cellulosic matter complex". (emphasis added)

> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).....If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) MPEP §2143.01.

Thus, the modification required of the prior art to achieve the invention would completely change the principal of operation of the prior art being modified.

On page 13 of the Office Action, the Examiner points to page 9, lines 5-9, of Shani. However, page 7, lines 26-34 of Shani fully state,

> According to one aspect of the present invention there is provided a process of expressing a recombinant protein in a plant and of isolating the recombinant protein from the plant, the process comprising the steps of (a) providing a plant, a plant derived tissue or cultured plant cells expressing a fusion protein including the recombinant protein and a cellulose binding peptide being fused thereto, **the fusion protein being compartmentalized within cells of the plant, plant derived tissue or cultured plant cells, so as to be sequestered from cell walls** of the cells of the plant, plant derived tissue or cultured plant cells (emphasis added)

However, this disclosure does not mean that fusion protein does not bind to cell wall or other cellulosic matter from the plant. This is evident from the rest of the first paragraph of the Summary of the Invention, which states for (b),

(b) homogenizing the plant, plant derived tissue or cultured plant cells, **so as to bring into contact the fusion protein with a cellulosic matter**...**to thereby effect affinity binding of the fusion protein via the cellulose binding peptide to the cellulosic matter, thereby obtaining a fusion protein cellulosic matter complex** (emphasis added)

As such, the instant invention cannot be achieved by the combined teachings of Haynes et al. and Shani et al. and there is further no suggestion or motivation to modify the reference teachings to achieve the instant invention. Withdrawal of the rejection is, therefore, respectfully requested.

In view of the above amendments and Remarks, Applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, PhD, Reg. No. 40,069 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By_____

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